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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,667	01/25/2002	Scott Smith	760-12 DIV	4339

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EXAMINER	
AFTERGUT, JEFF H	

ART UNIT	PAPER NUMBER
1733	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,667	SMITH, SCOTT	
	Examiner	Art Unit	
	Jeff H. Aftergut	1733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 5, 6, 8-11, 14, 16, 17, 20, 21, 23, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al (US 5,824,040) in view of any one of Nolting et al (US 6,488,701), Shull et al (US 6,143,022) or Schmitt (US 5,527,353) either combined alone or further optionally in view of any one of Pinchuk '913, Pinchuk '958, or Pinchuk '877 for the same reasons as expressed in paragraph 2 of the Office action dated September 27, 2004.

3. Claim1-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as set forth above in paragraph 2 further taken with either one of Shannon et al (US 5,928,279) or Brauker et al (US 6,517,571) for the same reasons as expressed in paragraph 3 of the Office action dated September 27, 2004.

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as set forth above in paragraph 2 further taken with Martin et al (US 6,361,637) for the same reasons as expressed in paragraph 4 of the Office action dated September 27, 2004.

Response to Arguments

5. Applicant's arguments filed December 9, 2004 have been fully considered but they are not persuasive.

The applicant essentially argues that none of the prior art of record taught or suggested that one skilled in the art would have formed a substantially planar strip and

wire assembly comprising a graft strip formed by extruding, casting or molding and an essentially flat planar stent wire and helically winding the substantially planar strip and wire assembly to form a tubular graft. It should be noted that the reference to Cox et al suggested the generic concept defined in the claim, namely the association of a planar strip of material with a wire assembly wherein the planar strip portion formed the graft material and the planar wire assembly formed the stent portion. While the stent portion did appear to include cross over of the wire, as previously expressed such was not a significant third dimension and the stent component in Cox et al was substantially planar inasmuch as such could include the cross over of the wire in the diamond shaped pattern as specified previously. The reference to Cox did suggest that the strip material was of a woven configuration but it did also state that rather than using Dacron fibers which were woven one skilled in the art would have known to utilize expanded ptfe for the graft component.

While it is agreed that each one of the references to Nolting et al, Shull et al, or Schmitt suggested that one skilled in the art would have formed the stent graft assembly in a different manner from that defined by the claims, the applicant is advised that one cannot show non-obviousness by attacking references individually where combination of references have been applied under 35 USC 103. More specifically, one must consider what the prior art as a whole would have suggested to the ordinary artisan. Here, one would have readily understood that the expanded ptfe referred to by Cox et al (see column 12, lines 7-14, note that the reference to PTFE material does not expressly state that the ptfe is in the form of a strand in use) would have included a strip of

expanded ptfe material for the graft as the references to any one of Nolting et al, Shull et al, or Schmitt suggested that those skilled in the art would have known to utilize a strip of expanded ptfe for a graft material in a stent graft assembly wherein the graft material in the form of a strip was wound to form the graft component. The applicant is advised that those skilled in the art would have understood that within the context of Cox et al that suitable graft strip material would have included a strip material in the form of expanded ptfe which was not a textile material but rather was a tape or strip of expanded ptfe. It should be noted that applicant did not dispute that it was notoriously well known to form a strip of expanded ptfe via extrusion, casting or molding and such is taken as conventional in the art of forming ptfe in a tape or strip form. It should be noted as addressed in the Office action dated September 27, 2004 that the claims at hand do not exclude the formation of a stent component with stent wires which cross over each other in the formation of the stent component. As such, the rejection need not rely upon the references to Pinchuk as discussed above.

The applicant is advised that one is not ignoring the various processing steps performed by Nolting, Shull or Schmitt, rather these process steps need not be directly considered in the question of obviousness. One skilled in the art would have understood that the processing of Cox as disclosed would have been a suitable manner useful for forming the stent graft assembly. The question to be answered here is would it have been obvious to employ the specific strip graft material as claimed (and possibly would it have been obvious to employ a flat and planar stent component, however it is believed that Cox suggested such a flat planar stent component on its face). To resolve

this question, the references to Nolting, Schmitt, and Shull were all cited to expressly show that those skilled in the art at the time the invention was made would have known to employ a ptfe material in the form of a strip of material (a non-woven arrangement) which was typically formed via extrusion, molding or casting, wherein the strip was capable of being wound upon a mandrel to form a graft material. The reference to Cox simply did not expressly state that the strip was in the form of a tape which was extruded, cast or molded and one skilled in the art would have been expected to look to the relevant art to determine exactly what the nature of the strip material formed from PTFE in Cox was. Here, they would have concluded that a ptfe tape formed via extrusion, casting or molding would have been suitable in the processing of Cox as the references to any one of Shull, Schmitt, or Nolting all suggested such a material was suitable and was wound upon a mandrel to form a graft component of a stent graft.

In any event, the formation of a stent component which did not incorporate a cross over of a wire was well known to those of ordinary skill in the art as evidenced by any one of Pinchuk '913, Pinchuk '958, or Pinchuk '877. Each one of the references to Pinchuk '913, Pinchuk '958, or Pinchuk '877 all suggested that those skilled in the art would have known that a stent component of a stent assembly would have been in the form of a wire which was sinusoidally preformed and subsequently helically wound n a mandrel. It should be noted that Cox suggested the performing of the stent component (to provide the diamond pattern) followed by helically winding the same to form the stent component). Clearly, to form a stent component which was substantially planar was known to those of ordinary skill in the art. More specifically, while none of Pinchuk '913,

Pinchuk '958, or Pinchuk '877 expressly state the association of their stents with a graft material, they do all suggest that a stent arrangement with a diamond like pattern with cross over wires was known to the artisan (see Gianturco US Patent 4,580,568 at column 2, lines 16-19 of Pinchuk '958, column 2, lines 7-14 of Pinchuk '913 and column 2, lines 4-11 of Pinchuk '877). Note the reference to Gianturco cited herein. Note that the stent assembly has a diamond shape pattern similar to that suggested by Cox (Figure 5e) with a wire cross over. Note that Pinchuk '877 and '958 both suggested that this arrangement had disadvantages in that such a structure is somewhat unsymmetrical and it may be subject to reocclusion due to the vary large open space that is typically present between the wires of the device. Clearly, to utilize the arrangement of Pinchuk '877, '958, or '913 would have avoided these problems and thus one would have been motivated to look to the arrangements defined therein for the stent components.

The applicant argues that there has been a hindsight reconstruction of the claims, however as expressed above there is ample reason to believe that one skilled in the art would have looked to the references of any one of Shull, Nolting, or Schmitt to provide support for the conclusion that one skilled in the art reading Cox would have understood that the ptfe strip material utilized therein was in fact a ptfe strip or tape which was formed by casting, extrusion or molding. Additionally, the references to Pinchuk '877, '958, or '913 all suggested that those skilled in the art would have desired to utilize the specified stent arrangement in order to provide a stent component with smaller openings and less chance of reocclusion as well as more symmetrical in nature.

The claimed invention would have been obvious to the ordinary artisan, and it is not seen where, as here, specific reasons for making the rejection have been provided how one can consider such a rejection to have been made in hindsight.

Regarding the references to Shannon and Brauker, again applicant takes to position that these references teach away from the claimed invention in that they suggest that those skilled in the art would have utilized different processing to provide the assembly as claimed. These references were not cited for the specific processing as the reference to Cox expressly suggested the same. There references were cited to show the specific material utilized to make a stent graft assembly and to further suggest that the ordinary artisan would have embedded the stent component between two graft components in order to ensure that the stent in the assembly was not exposed in use, i.e. that there were smooth exterior surfaces in the finished assembly. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the materials of either one of Shannon et al or Brauker et al in the operation of Cox et al as such would have been recognized as conventional materials utilized by the ordinary artisan in the course of manufacturing a stent graft. Additionally, to provide the stent material such hat it was encapsulated between the graft materials in strip form prior to winding would have been obvious to the ordinary artisan as: (1) Cox et al provided the completed assembly prior to winding the assembly about the mandrel, and; (2) the references to Shannon et al or Brauker et al suggested that in a stent graft assembly the stent materials would have been embedded between two graft materials.

Regarding Martin, one skilled in the art would have selected a suitable material for the stent component and such would have included nitinol as was a known compound useful for a stent component in a stent assembly. It would have been within the purview of the ordinary artisan to select suitable materials for use in the operation of Cox and such would have certainly included the use of a nitinol wire for the stent component as such nitinol was a conventional material useful for a stent assembly.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gianturco is discussed in the Pinchuk references and teaches a diamond shaped zigzag pattern for a stent component.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff H. Aftergut whose telephone number is 571-272-1212. The examiner can normally be reached on Monday-Friday 7:15-345 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on 571-272-1156. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeff H. Aftergut
Primary Examiner
Art Unit 1733

JHA
February 14, 2005